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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/750,086	12/29/2000	David L, Reynolds	31506-0060	6372

1059 7590 03/29/2004

BERESKIN AND PARR
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TORONTO, ON M5H 3Y2
CANADA

EXAMINER

MENDEZ, MANUEL A

ART UNIT	PAPER NUMBER
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3763

18

DATE MAILED: 03/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/750,086

Applicant(s)

REYNOLDS ET AL.

Examiner

Manuel Mendez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 7, 10 and 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8, 9 and 12 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

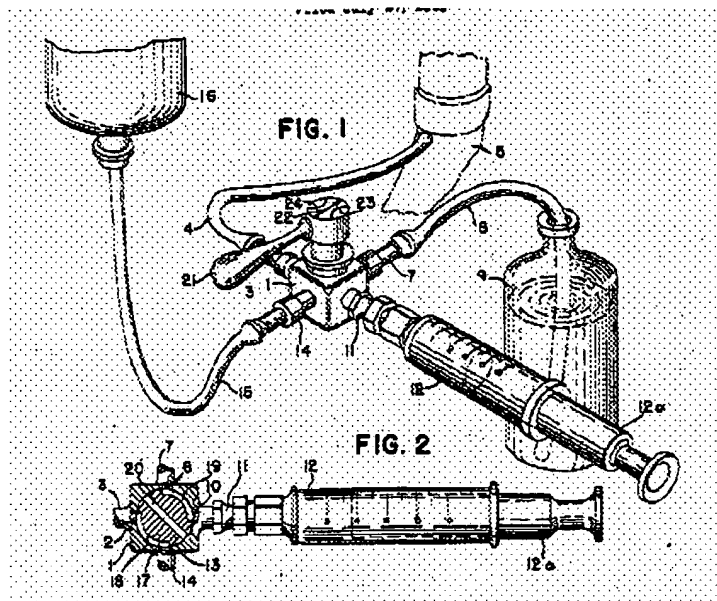
Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6, 8, 9, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over (**Pennington**, U.S. Patent No. 2,485,842, **Schweser**, U.S. Patent No. 2,032,723, and/or **McCarty**, U.S. Patent No. 5,439,452) in view of (**Haber, et al.**, U.S. Patent No. 5,562,616, **Morell**, U.S. Patent No. 5,389,070, **Lynn, et al.**, U.S. Patent No. 5,549,569, and **Nowakowski**, U.S. Patent No. 6,159,232, and/or **Brenneman**, U.S. Patent No. 5,466,220).



The **Pennington Patent** shows in figure 1 (above), a delivery system comprising a first container comprising fluid displacement means, a second container, a body comprising a diverter valve, and first, second and third vessels extending to open ends from the diverter valve, a first socket and a second socket, a tubulation (12) for delivery of the pharmaceutical wherein the first container is adapted to fluidly couple to the first vessel and the second container is adapted to fluidly couple to the second vessel.

The Schweser and McCarty Patents also disclose delivery systems having the limitations presented in claim 1. Accordingly, based on the teachings of the first three cited patents, it is conventional in the art to use a diverter valve to provide communication between the various containers and the infusion syringe. Moreover, it is also conventional to design the valve to selectively provide fluid communication between any of the containers at any particular sequence before the infusion step using the syringe. Consequentially, for a person of ordinary skill in the art, designing a diverter valve to provide fluid communication between the containers and the syringe

before the step of infusing the drug(s), would have been considered an obvious design choice. Similarly, the particular arrangement of the containers around the diverter valve would have also been consider an obvious design choice.

Finally, in order to positively address all the possible embodiment variations with respect to the sockets and the various medical dispensers used in communication with the diverter valve, the examiner of record has included in this rejection **Haber, et al.**, U.S. Patent No. 5,562,616, **Morell**, U.S. Patent No. 5,389,070, **Lynn, et al.**, U.S. Patent No. 5,549,569, and **Nowakowski**, U.S. Patent No. 6,159,232, and/or **Brenneman**, U.S. Patent No. 5,466,220. Accordingly, for a person of ordinary skill in the art, designing sockets to connect drug containers, vials, and syringes with a diverter valve, would have also been considered an obvious design choice. Such enhancement would have facilitated the transfer and mixing of fluid before infusion, enhancing the capabilities of the diverter valve.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

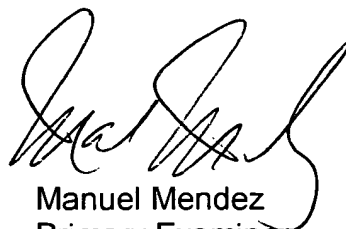
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manuel Mendez whose telephone number is 703-308-2221. The examiner can normally be reached on 0730-1800 hrs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Brian Casler can be reached on 703-308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.



Manuel Mendez
Primary Examiner
Art Unit 3763

MM

March 20, 2004